

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in December 2011.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-325

Trade Name: Incurin™
Ingredients: Estriol
Sponsor: Intervet, Inc.
Approval Date: July 24, 2011
Status: Rx
Route: Oral
Species: Dog, ovariectomized females
Drug Form: Single-scored tablet
Concentration: 1 mg of estriol per tablet
Indications: For the control of estrogen-responsive urinary incontinence in ovariectomized female dogs.
Exclusivity: 5 years

21 CFR 520.852 76 FR 78149-78150

NADA Number: 141-329

Trade Name: Atopica® for Cats
Ingredients: Cyclosporine oral solution, USP MODIFIED
Sponsor: Novartis Animal Health US, Inc.
Approval Date: August 8, 2011
Status: Rx
Route: Oral
Species: Cats
Drug Form: Oral solution
Concentration: 100 mg/mL
Indications: Atopica® for Cats is indicated for the control of feline allergic dermatitis as manifested by excoriations (including facial and neck), military dermatitis, eosinophilic plaques, and self-induced alopecia in cats at least 6 months of age and at least 3 lbs (1.4 kg) in body weight.
Exclusivity: 3 years
Patent: Patent Number Expiration date:
6,258,808 June 25, 2012
6,262,022 June 25, 2012

21 CFR 520.522 76 FR 78815-78816

NADA Number: 141-330

Trade Name: Easotic®
Ingredients: Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate
Sponsor: Virbac AH, Inc.
Approval Date: October 31, 2011
Status: Rx
Route: Otic
Species: Dogs
Drug Form: Otic suspension
Concentration: 1.11 mg/mL hydrocortisone aceponate, 15.1 mg/mL miconazole nitrate, 1.5 mg/mL gentamicin sulfate
Indications: Easotic® suspension is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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Exclusivity: 3 years

21 CFR 524.1132 76 FR 78150

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-064

Trade Name: Pulmotil® 90
Ingredients: Tilimicosin phosphate
Sponsor: Elanco Animal Health, A division of Eli Lilly & Co.
Approval Date: August 19, 2011

The supplemental NADA provides for the use of tilimicosin Type C medicated feeds by veterinary feed directive for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in groups of beef and nonlactating dairy cattle where active BRD has been diagnosed in at least 10 percent of the animals in the group.

21 CFR 558.4 and 558.618 76 FR 76894-76895

NADA Number: 95-735

Trade Name: Rumensin® 90
Ingredients: Monensin, USP
Sponsor: Elanco Animal Health, A division of Eli Lilly & Co.
Approval Date: May 24, 2011

The supplemental NADA revises the percent monensin Type A medicated article in the codified free-choice feed specifications to reflect use of a product containing 90.7 grams of monensin per pound.

21 CFR 558.355 76 FR 79064-79065

ANADA Number: 200-318

Trade Name: Bimectin® Pour-On
Pioneer: Ivomec® Pour-On
Ingredients: Ivermectin
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: September 21, 2011

This supplemental ANADA provides for approval of the proprietary name Bimectin® Pour-On and updates to the persistent activity statement to be consistent with the reference listed new animal drug as follows: Bimectin® (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

21 CFR 524.1193 76 FR 81806-81807

Sponsor Change

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The following corrections or additions to the list were published in the Federal Register in December 2011.

NADA Number: 141-217

Previous: Technology Transfer, Inc.

New Sponsor: Ark Sciences, Inc.

Drug Labeler Code: 076175

21 CFR 522.2690 and 510.600 76 FR 79064